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10/562,392	12/19/2005	Fernando Bouffard Fita	14455.876US01	8090

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EXAMINER	
KAROL, JODY LYNN	
ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
12/18/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/562,392	FITA, FERNANDO BOUFFARD	
	Examiner	Art Unit	
	Jody L. Karol	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/14/2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-12,14,15,17,19,20,22 and 24-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-12, 14-15, 17, 19-20, 22, and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/14/2009 has been entered.

Receipt is acknowledged of applicant's Amendment/Remarks filed 10/14/2009. Claims 1 and 26 have been amended. Claims 6, 13, 16, 18, 21, and 23 are cancelled. Claims 1-5, 7-12, 14-15, 17, 19-20, 22, and 24-26 are pending and are currently under consideration.

WITHDRAWN REJECTIONS

2. In view of Applicant's amendment to claim 26, the rejection of claim 26 under 35 U.S.C. 112, 2nd paragraph, as being indefinite, is herein withdrawn.

MAINTAINED REJECTIONS

3. The following rejections have been maintained from the previous Office Action dated 4/14/2009, but have been slightly modified to address Applicant's claim amendments to claims 1 and 26:

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-5, 7-12, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cassel (US 2002/0128285).

The instant claims are directed to compositions for topical administration comprising therapeutically safe and effective amounts of lidocaine, prilocaine, and tetracaine or pharmaceutically acceptable salts thereof, wherein the pharmaceutical composition is administered without occlusion, and a method of eliciting an anesthetic effect by administering said composition topically without occlusion.

Cassel teaches topical delivery of a local anesthetic in a pharmaceutically acceptable topical drug formulation to an exterior surface of a surgically closed wound

(see abstract and page 2, section [0025]). Cassel further teaches that the preferred local anesthetics include lidocaine, prilocaine, and tetracaine (see page 2, section [0028]) and that the local anesthetics may be combined in a pharmaceutically acceptable topical formulation, with a preferred combination containing lidocaine and prilocaine, and another containing lidocaine and tetracaine (see page 3, section [0030]). Cassel also teaches lidocaine and prilocaine as a eutectic mixture as claimed in the instant claim 3, wherein lidocaine is present in 1 to 40% by weight and prilocaine is present in 0.5 to 40% by weight, which overlaps or encompasses the ranges as claimed for these components in the instant claims 4-5, and 25 (see page 4, section [0057]). Cassel also teaches that the preferred amounts for the lidocaine and tetracaine composition are lidocaine in 1 to 40% by weight and tetracaine in 0.5 to 40% by weight, which overlaps or encompasses the ranges as claimed for these components in the instant claims 4-5, 7, and 25 (see page 4, section [0058]). Cassel teaches that these compositions comprise carriers systems including buffered solutions (meaning the formulation contains water) or other art-known carriers, and that the any pharmaceutically acceptable excipient is acceptable, wherein the compositions are in the form of a gel, cream, or ointment as claimed in the instant claims 2, 8, and 24 (see page 3, section [0038] and page 4, section [0055], and page 5, section [0061]). Cassel teaches that penetration enhancers may be used in the formulations, and include N-methyl pyrrolidone as claimed in the instant claims 9-12, and 25 (see page 5, section [0065]). Cassel further teaches methods of using the compositions comprising topically applying the compositions to the exterior surface of a wound as claimed in the instant

claim 26 (see page 5, Example I, and claim 1 for example). Cassel teaches the application of a "dressing" or occlusion is optional.

Cassel does not explicitly teach a composition comprising a combination of lidocaine, prilocaine, and tetracaine. Cassel also does not explicitly teach compositions comprising the amounts of the components (i.e. anesthetics and methyl pyrrolidone) as claimed in the instant claims 4-5, 7, 11-12, and 25.

However, it would have been obvious to one of ordinary skill in the art at the time of the invention, to combine the lidocaine/prilocaine composition with the lidocaine/tetracaine composition as taught by Cassel, to form a third composition comprising all three anesthetic agents. One of ordinary skill in the art would have been motivated to do so because both prior art compositions have utility as topical anesthetic compositions, and the combination of the compositions is claimed to have utility as a topical anesthetic composition. It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose (See *In re Kerkhoven*, 626 F.2d 846, 205, U.S.P.Q. 1069 (C.C.P.A. 1980)).

Furthermore, while the references do not explicitly teach the claimed amounts of anesthetic agents or methyl pyrrolidone, the determination of optimal or workable amount of these components by routine experimentation is obvious absent showing of criticality of the claimed amounts. One having ordinary skill in the art would have been motivated to optimize the amounts of the herein claimed anesthetics in order to obtain a composition with the desired anesthetic properties and desired skin penetrating effect.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time it was made.

6. Claims 1-5, 7-9, 19-20, 22, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samuels et al. (US 2002/0006435 A1).

Samuels et al. teaches compositions for topical application comprising a therapeutically effective amount of topical anesthetic and a pharmaceutically carrier, and methods of administering the composition to a mammal (see abstract). Samuels et al. teaches that the compositions comprise 0.5 to 20% by weight of anesthetic agents, (see page 1, section [0015]), that preferred agents include lidocaine, prilocaine, and tetracaine, and that preferably the anesthetic is eutectic mixture of anesthetics (see page 2-3, section [0035]). In a specific embodiments, Samuels et al. teaches a eutectic mixture of 3.5 % by weight lidocaine, 2.5% by weight prilocaine, and 1.5% by weight dibucaine (see page 3, section [0039], and page 8, Example 4), a eutectic mixture of 2.5% by weight lidocaine and 2.5% by weight prilocaine also comprising water as claimed in the instant claims 2-3 (see page 3, sections [0040]-[0041] and page 8, Example 5), and a mixture 12% by weight lidocaine and 12% by weight tetracaine hydrochloride (see page 9, Example 6). Samuels et al. further teaches that the compositions may be formulated as creams, lotions solutions, gels or sprays, and contains carriers such as emollients, emulsifiers, thickening agents, surfactants, etc. as claimed in the instant claims 8-9, and 24 (see page 4, section [0056]). Samuels et al. teaches that thickeners include gelling agents such as carbopol (carbomer), and that

gums such as guar gum may also be incorporated into the composition as claimed in the instant claims 19-20 and 25 (see page 4, section [0060] and page 7, section [0100]. Samuels et al. further teaches that the compositions may comprise 0.5 to 2% by weight surfactant, and include nonionic surfactant such as polysorbate 20 (Tween 20), and polysorbate 80 (Tween 80) as claimed in the instant claims 9, 2, and 25 (see page 5, sections [0070] and [0073]). Samuels et al. also teaches methods of administering the composition comprising contacting the skin with said composition as claimed in the instant claim 26 (see page 7, sections [0108]-[0110]). It is noted that Samuels et al. do not teach administering the compositions with occlusion, and thus occlusions are not deemed as a critical component.

Samuels et al. does not explicitly teach a composition comprising a combination of lidocaine, prilocaine, and tetracaine. Samuels et al. also does not explicitly teach compositions comprising the amounts of the components (i.e. anesthetics and methyl pyrrolidone) as claimed in the instant claims 4-5, 7, 19-20 and 25.

However, it would have been obvious to one of ordinary skill in the art at the time of the invention, to combine the lidocaine/prilocaine composition with the lidocaine/ tetracaine composition as taught by Samuels et al., to form a third composition comprising all three anesthetic agents. One of ordinary skill in the art would have been motivated to do so because both prior art compositions have utility as topical anesthetic compositions, and the combination of the compositions is claimed to have utility as a topical anesthetic composition. It is obvious to combine individual compositions taught

to have the same utility to form a new composition for the very same purpose (See *In re Kerkhoven*, 626 F.2d 846, 205, U.S.P.Q. 1069 (C.C.P.A. 1980)).

Furthermore, while the references do not explicitly teach the claimed amounts of anesthetic agents or viscosity increasing agent (thickener), the determination of optimal or workable amount of these components by routine experimentation is obvious absent showing of criticality of the claimed amounts. One having ordinary skill in the art would have been motivated to do this in order to obtain a composition with the desired anesthetic properties and viscosity. Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time it was made.

7. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cassel (US 2002/0128285) as applied to claims 1-5, 7-12, 24, and 26 above, and further in view of Lutz et al. (US 5,750,139).

Cassel is described above as applied to claims 1-5, 7-12, 24, and 26.

Cassel does not teach dimethyl sulfoxide, nor the amount present in the composition, as a penetration enhancer as claimed in the instant claims 14-15. Lutz et al. teaches that suitable solvents having penetration-enhancing properties are skin-tolerated penetration enhancers such as dimethyl sulfoxide (DMSO) or N-methylpyrrolidone (see column 8, lines 44-49).

It would have been obvious to one of ordinary skill in the art at the time of the invention, to substitute DMSO for N-methylpyrrolidone in the compositions taught and made obvious by Cassel. One of ordinary skill in the art would have been motivated to

do because both DMSO and methyl pyrrolidone are art-recognized penetration enhancers as taught by Lutz et al. Furthermore, the determination of optimal or workable amount of DMSO by routine experimentation is obvious absent showing of criticality of the claimed amount. One having ordinary skill in the art would have been motivated to optimize the amount of DMSO in order to obtain a composition with the desired skin-penetrating effects. Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time it was made.

8. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cassel (US 2002/0128285) as applied to claims 1-5, 7-12, 24, and 26 above, and further in view of Santana et al. (US 2003/0103955 A1).

Cassel is described above as applied to claims 1-5, 7-12, 24, and 26.

Cassel does not teach hyaluronidases or derivatives of mucopolysaccharides as a spreading agent in the compositions as claimed in the instant claim 17.

Santana et al. teaches topical compositions comprising diclofenac, papain, hyaluronidase, and vitamin E (see abstract). Santana et al. further teaches that the use of hyaluronidase as a diffusion factor (spreading agent) is known, and is compositions comprising the hyaluronidase have a high rate of penetration through the skin (see page 1, section [0012] and page 2, section [0016]).

It has been held that the selection of a known material based on its suitability for its intended use supported a *prima facia* obviousness
determination in *Sinclair & Carroll Co. V. Interchemical Corp.,* 325 U.S. 327, 65 USPQ

297 (1945). Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the compositions taught or made obvious by Cassel by adding the spreading agent hyaluronidase as taught by Santana et al.

One of ordinary skill in the art would have a reasonable expectation of success in combining the above recited components, since it has been reasoned that reading a list and selecting a known compound to meet known requirements in no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle. *Sinclair & Carroll Co.,* 325 U.S. at 335, 65 USPQ at 301. Since all elements of the instant claims are taught in the cited references to be employed in topical compositions, combining the components for their intended use would have been *prima facia* obvious.

NEW REJECTIONS

9. After further consideration, the following rejections have been newly added:

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 25 contains the trademark/trade names Tween® 20 and Tween® 80. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A

trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe polyoxyethylenesorbitan monolaurate and polyoxyethylenesorbitan monooleate, accordingly, the identification/description is indefinite.

It is noted that polyoxyethylenesorbitan monolaurate and polyoxyethylenesorbitan monooleate along with their respective CAS Nos. are listed in parentheses. The Examiner suggests replacing the trademark/trade names Tween® 20 and Tween® 80 solely with polyoxyethylenesorbitan monolaurate and polyoxyethylenesorbitan monooleate and deleting the items in parentheses.

Response to Arguments

11. Applicant's arguments filed 10/14/2009 have been fully considered but they are not persuasive.

Applicant argues that the data provided supports the improved effects of the present composition alone as well in view of EMLA (i.e. effectiveness over a period of less time without an occlusion), and this sufficient effectiveness without necessity of a one-to-one showing. Applicant also alleges there is a demonstrated synergistic effect in the decrease of side effects with the three anesthetics compared to the 2-component combinations (see Tables 2 and 3), and that prilocaine stabilizes tetracaine. In response it is respectfully submitted that it is applicant's burden to demonstrate

unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

As stated in the 4/14/2009 Office Action, the evidence presented is not reasonably commensurate in scope with the scope of the subject matter claimed. Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the “objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support.” In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980). In the instant case, only one specific formulation is provided as evidence, which does not provide basis upon which one can reasonably extrapolate and conclude that the unexpected results would be present in all the claimed compositions. For example, the formulation is limited to an amount of 1.5% (w/w) for each anesthetic, but several of the claims do not recite any specific amount of anesthetic. The formulation also contains many additional specific excipients that are not recited in all of the claimed formulations. It is unclear whether the presence of these excipients is

critical/necessary to obtain the unexpected results. Furthermore, it is not clearly seen how the decrease in side effects observed is a demonstrable synergistic effect (see Tables 2 and 3). To demonstrate a synergistic decrease in side effects, the sum of each of the side effects taken separately (i.e. by each anesthetic alone) must be greater than the side effects demonstrated by the combination of the three anesthetics. It is also noted that the amount of total amount of anesthetic in the EMLA cream is 5.0%, whereas the total amount of anesthetic in the claimed invention is only 4.5%. Thus, a lesser amount of side effects is expected, because a less amount of anesthetic is applied. Lastly, while Applicant's assert the presence of prilocaine stabilizes the tetracaine in the composition of the instant invention, the Applicant's data is entirely bereft of any statement or evidence that would demonstrate tetracaine is stabilized by prilocaine. Therefore, no clear and convincing unexpected benefit is seen to be present herein.

The Applicant further argues that the claimed compound is structurally distinct over the state of the art in that includes the claimed feature of not needing occlusion. The Examiner respectfully disagrees. Claim 1 recites "wherein the pharmaceutical composition is administered without an occlusion" which is viewed as an intended use, and not a structural difference in the composition itself. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In support of this, Cassel teaches application of a "dressing" or

occlusion after application of the topical anesthetic is optional (see page 3, section [0039]).

The Applicant further argues that there is no motivation in Cassel or Samuels to make the present combination merely because each of the prior art compositions have separate discrete utilities as topical anesthetics, because the present combination has unpredictable different and new purposes. The Examiner respectfully disagrees. It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose *In re Kerkhoven*, 626 F.2d 846, 205, U.S.P.Q. 1069 (C.C.P.A. 1980). Further, the motivation to combine need not be Applicant's motivation to invent. *In re Dillion*, 16 2d 1897 (Fed. Cir. 1990). The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicant argues that Samuels solves a different problem and that the composition of the instant invention is not for the same purpose. As stated above, Applicant's reasons for inventing the composition need not be the same motivation gleaned from the prior art to combine the anesthetic compositions.

The Applicant further alleges that Samuels teaches away from adding a third anesthetic because Samuels teaches adding a vasodilator to lengthen effect, hence giving up on the field of anesthetics alone to lengthen time. It is respectfully submitted that Samuels does not teach away from Applicant's solution because it does not

discredit, discourage, or dissuade the ordinary skilled artisan from adding a third anesthetic.

Applicant argues that Lutz et al. is directed to benzopyrone and the dermal application thereof, and that Lutz et al. is non-analogous art because benzopyrone is used for venous, vascular diseases, protein-rich edemas, and protein-rich lymphedemas, particularly for chronic venous insufficiency, phlebitis, and cancers. The Applicant also argues that requires a neutral or carboxylic acid-based active ingredient while the compositions of the instant invention do not require said ingredient. The Examiner respectfully disagrees. Lutz et al. is relied upon as a secondary reference solely to demonstrate DMSO and N-methyl pyrrolidone are conventionally used as solvents in topical compositions because of their skin-tolerated penetration enhancing properties. The active ingredient taught by Lutz et al. is not deemed necessary for DMSO and N-methyl pyrrolidone to act as solvents with skin-tolerated penetration enhancing properties. Thus, it would be obvious to include DMSO and N-methyl pyrrolidone in topical formulations such as those taught by Cassel to enhance the skin penetration of the topical formulation. The optimization of the amount of said components in topical compositions is deemed as with the purview of the ordinary artisan.

Applicant argues that Santana et al. do not teach mucopolysaccharides but is limited to hyaluronidases. It is respectfully submitted that claim 17 requires mucopolysaccharides **or** hyaluronidases, and thus the teaching of hyaluronidases by Santana et al. is sufficient.

Applicant further argues that Santana et al. non-analogous art because hyaluronidase is taught as a part of a three-element composition of diclofenac, wherein diclofenac has an anti-inflammatory effect and is used, i.e., to treat arthritis. The Examiner respectfully disagrees. Santana et al. is relied upon solely as a secondary reference to demonstrate hyaluronidases are conventionally used as diffusion factors (spreading agents) in topical compositions because of their ability to increase penetration of the composition through the skin, regardless of the presence or absence of diclofenac. Thus, it would be obvious to include hyaluronidases in topical formulations such as those taught by Cassel to enhance the skin penetration of the formulation.

Thus, for these reasons, Applicant's arguments are found unpersuasive. Said rejection is maintained. Said rejections are maintained, and the instant claims are still considered properly rejected under 35 USC 103(a).

Conclusion

No claims are allowed.

Correspondence

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Jody L. Karol/

Examiner, Art Unit 1627

/Yong S. Chong/
Primary Examiner, Art Unit 1627